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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/755,985      | 01/13/2004  | Brian Blischak       | 02-036 US           | 2245             |

35320 7590 11/27/2006

ADVANCED NEUROMODULATION SYSTEMS, INC.  
6901 PRESTON ROAD  
PLANO, TX 75024

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| EXAMINER |
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MCCORKLE, MELISSA A

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3763

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                 |                                 |  |
|------------------------------|---------------------------------|---------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/755,985   | Applicant(s)<br>BLISCHAK, BRIAN |  |
|                              | Examiner<br>Melissa A. McCorkle | Art Unit<br>3763                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-26 and 49-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-26 & 49-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 18-26 and 49-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Tucker et al (4,193,397.) Tucker discloses a method comprising manually applying pressure to a working fluid container in an actuator associated with an implantable pharmaceutical fluid delivery device, wherein the implantable pharmaceutical fluid delivery device comprises a first fluid reservoir and a second fluid reservoir, thereby causing a flow of the working fluid into the first fluid reservoir; delivery to the treatment area a first dosage of pharmaceutical fluid from a constant flow pump as the first dosage is delivered, the constant flow pump associated with the implantable pharmaceutical delivery device; wherein the constant flow pump does not comprise an electrical motor or electrical power supply; or wherein the first dosage is a bolus dosage; or further comprising drawing working fluid from the first fluid reservoir into the actuator, wherein said drawing causes a filling of the second fluid reservoir with pharmaceutical fluid; or wherein the first dosage is a supplemental flow dosage, wherein the delivering to the treatment area a first dosage comprises drawing the working fluid into the actuator from the first fluid reservoir thereby causing pharmaceutical fluid to be expelled from the second fluid reservoir; or wherein the first and second fluid reservoirs are piston and cylinder devices; or wherein the actuator is selected from the group consisting of a compressible button and a bulb [see column 9, line 39-column 11, line 68.]

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3. Tucker discloses a method of operating an implantable infusion drug pump, comprising storing infusate in a main reservoir of the implantable infusion drug pump, wherein a substantially constant fluid pressure is provided to the infusate in the main reservoir, driving infusate from the main reservoir through a flow restrictor and out through a discharge port of the implantable infusion drug pump at a substantially constant basal infusion rate; providing a temporary bolus infusion rate in response to patient manipulation of an actuator of the implantable infusion drug pump, wherein the bolus infusion rate is provided simultaneously to the basal infusion rate, wherein providing a temporary bolus infusion rate comprises drawing infusate from the main reservoir into a secondary reservoir using the actuator, and controlling a discharge rate from the secondary reservoir to the discharge port using a flow restrictor; wherein the implantable infusion drug pump does not comprise an electrical motor or and electrical power supply. He discloses the method as stated above wherein the drug pump comprises at least one one-way valve that enables the secondary reservoir to be filled without being subjected to a flow rate limitation of a flow restrictor of the implantable drug infusion pump; or wherein the actuator drives working fluid into a working fluid reservoir that is mechanically coupled to the secondary reservoir; wherein the secondary and working fluid reservoirs are defined by respective piston cylinders; wherein the secondary reservoir is adapted to hold a maximum fluid volume that is greater than a maximum fluid volume of the working fluid reservoir; wherein the driving infusate from the main reservoir is performed by an elastomeric diaphragm [see column 9, line 39-column 11, line 68, fig 2 and 5].

*Response to Arguments*

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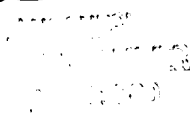
4. Applicant's arguments with respect to claims 18-26 have been considered but are moot in view of the new ground(s) of rejection.

#### **Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melissa A McCorkle  
Examiner  
Art Unit 3763